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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,417	02/28/2002	Donald J. McMichael	KCX-518D (17507D)	3208
7590	12/17/2003		EXAMINER	
STEPHEN E. BONDURA, ESQ. DORITY & MANNING, P.A. P.O. BOX 1449 GREENVILLE, SC 29602-1449			BUI, LUAN KIM	
			ART UNIT	PAPER NUMBER
			3728	
			DATE MAILED: 12/17/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/085,417	MCMICHAEL ET AL.
	Examiner Luan K Bui	Art Unit 3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4, 8-12 and 14-21 is/are rejected.
- 7) Claim(s) 5-7 and 13 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \*    c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4-5</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 8-10, 12, 14-16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ross et al. (5,318,543; hereinafter Ross'543). Ross'543 discloses a kit (10) for holding surgical articles comprising a tray (13) having a plurality of planar surfaces are offset vertically including a first planar surface with a first planar recess for holding surgical articles (17, 27), a second planar surface with a second planar recess for holding surgical article (23) and a third planar surface with a third planar recess for holding surgical articles (14, 21, 22, 24), a removable container (20) containing surgical articles (18, 19) disposed within at least one of the planar surfaces and a cover (11). Ross'543 discloses the container (20) must be removed from the tray prior to access to the articles (17, 27). The kit of Ross'543 is inherently capable of holding articles to be utilized in a “push” percutaneous endoscopic gastrostomy procedure. As to claims 4 and 8, Ross'543 discloses at least one of the recesses contains at least a portion of a tube/PEG or feeding tube (14, 24). As to claim 9, Ross'543 discloses a container recess for holding the container (20) (see Figure 3). As to claim 10, Ross'543 discloses at least one boss member extending upwardly through at least a portion of one of the articles (23). As to claim 12, at least one of the articles (14, 24, 26) having an elongated tapered end. As to claim 15, Ross'543 discloses at least one recess contains an introducer cannula (26).

3. Claims 1, 2, 9-12 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalinski (5,311,990). Kalinski discloses a kit (10) for holding medical/surgical articles comprising a tray (80) having a plurality of planar surfaces offset vertically including a first planar surface (101) with a first planar recess defined by walls (90) for holding medical articles, a second planar surface (85) with a second planar recess for holding medical articles and a third planar surface (above 85 and next to a gun shape) with a third planar recess for holding article which is shown having a gun shape, a removable container (55) containing articles disposed within at least one of the planar surfaces and a cover (25). Kalinski discloses the container must be removed from the tray prior to access to the articles. The kit of Kalinski is inherently capable of holding articles to be utilized in a "push" percutaneous endoscopic gasstrostomy procedure. As to claims 10 and 11, Kalinski discloses at least one boss (next to the article having the gun shape) extended through a handle portion of the gun shape/snare device.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (5,318,543; hereinafter Ross'543) or Kalinski (5,311,990). Ross'543 or Kalinski discloses the kit as above having all the limitations of the claims except for the cover being formed from a permeable web. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the kit of Ross'543 or Kalinski so the cover is formed from a permeable web for sterilization.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-4, 8-12 and 14-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/085,630 and over claims 1-26 of copending Application No. 10/085,637 and over claims 1-21 of copending Application No. 10/085,639. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations in the claims of the instant patent application are fully disclosed by the copending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

8. Claims 5-7 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is (703) 305-5861. If in receiving this Office Action, it is apparent to Applicant that certain documents are missing from the record for example copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to TC 3700 Customer Service at (703) 306-5648.

Any inquiry of a general nature or relating to the status of this application should be directed to the Customer Service whose telephone number is (703) 872-9301. Facsimile correspondence for this application should be sent to (703) 872-9306 for Formal papers and After Final communications.

lkb  
December 11, 2003



Luan K. Bui  
Primary Examiner